

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/006,524	DUBOVI ET AL.	
	Examiner	Art Unit	

Mary E. Mosher, Ph.D. 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 2/28/03, 2/27/03, 9/24/02, 8/5/02, 4/1/02, 3/26/02.
2.  The allowed claim(s) is/are 3-19.
3.  The drawings filed on 01 April 2002 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some\* c)  None of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a)  The translation of the foreign language provisional application has been received.
6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
  - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

<input type="checkbox"/> Notice of References Cited (PTO-892)	<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	<input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.
<input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. <u>3/26/02, 2/27/03</u>	<input checked="" type="checkbox"/> Examiner's Amendment/Comment
<input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	<input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	<input type="checkbox"/> Other

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 and 2, drawn to a woodchuck infected with bovine diarrhea virus, classified in class 800, subclass 9.
- II. Claims 3-19, drawn to screening assays and isolated cells, classified in class 435, subclass 5 and 325, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the infected woodchuck, as claimed, can be used in a materially different process such as a model system for HCV liver pathology.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Stephanie Adams on December 12, 2003 an election was made without traverse to prosecute the invention of group II, claims 3-19.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephanie Adams on December 12, 2003.

The application has been amended as follows:

Claims 1 and 2, directed to the nonelected invention, have been cancelled.  
7. A method for identifying a compound with potential for treatment of Flaviviridae infection comprising:

- a) administering a test compound to a woodchuck infected with bovine viral diarrhea virus; and
- b) determining whether the test compound inhibits bovine diarrhea virus in the woodchuck;

wherein inhibition of bovine diarrhea virus identifies a compound with potential for treatment of Flaviviridae infection.

15. A method for identifying a compound with potential for treatment of Flaviviridae infection comprising:

- a) administering a test compound to a woodchuck cell infected with bovine viral diarrhea virus; and
- b) determining whether the test compound inhibits bovine diarrhea virus in the woodchuck cell;

wherein inhibition of bovine diarrhea virus identifies a compound with potential for treatment of Flaviviridae infection.

16. A method for identifying a compound with potential for treatment of Flaviviridae infection comprising:

- a) administering a test compound to a first woodchuck cell infected with bovine viral diarrhea virus;
- b) administering a control compound to a second woodchuck cell infected with bovine viral diarrhea virus; and
- c) determining whether the test compound inhibits bovine diarrhea virus in the first woodchuck cell more than the control compound inhibits bovine viral diarrhea virus in the second woodchuck cell;

wherein greater inhibition of bovine diarrhea virus in the first cell identifies a compound with potential for treatment of Flaviviridae infection.

In claim 8, in line 1, "identifying" has been changed to "selecting", and "with potential" has been inserted after "a compound".

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In claim 9, in line 1, "identifying" has been changed to "selecting", and "with potential" has been inserted after "a compound".

The following is an examiner's statement of reasons for allowance:

Claims 7-9 and 15-16 have been amended to clarify that the screening assay identifies drugs which are potentially active against members of the Flaviviridae, in recognition of the fact that few, if any, model systems are foolproof in predicting the efficacy of a drug for treatment of a different infectious agent in a different host.

Although the specification does not contain literal support for this limitation, the paragraph spanning pages 15-16 indicates that the assay is "generally predictive of results" for inhibiting hepatitis C and other flaviviruses. Therefore the specification reasonably conveys the concept that the assay is intended to be generally predictive, not absolutely predictive, and the teachings of the specification are sufficient to enable a method for identifying compounds with potential for therapeutic use.

Claims 7, 15, and 16 also have been completed by addition of a step that correlates the assay results to the purpose set forth in the preamble. Claims 8 and 9 have been amended so that the wording of the preamble and the correlation step is consistent. In the context of this application, "identifying a compound" and "selecting a compound" are seen as having the same meaning.

The prior art does not teach or suggest infection of woodchucks or woodchuck cells with bovine viral diarrhea virus (BVDV), or that the infected animal or cell would be useful in screening drugs intended for an ultimate use against other members of the Flaviviridae, such as hepatitis C. While the prior art teaches woodchucks and

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woodchuck hepatitis virus as a model system for hepatitis B infection, Hepatitis B and woodchuck hepatitis virus are hepadnaviruses completely unrelated to either BVDV or hepatitis C virus. The three conference abstracts by Jacob et al are not available as prior art, because the invention as claimed has an effective date of December 1, 2000; the April 2000 conference abstracts are not the work of "another", and the December conference is later than the effective date. The declaration of the inventors filed Feb 28, 2003 is not necessary to overcome the published abstracts, but it would be unconvincing if it were necessary, because it provides only unsupported assertion (not factual evidence) regarding the date of conception of the invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926 until approximately 1/8/2004, 571-272-0906 afterwards. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027 until approximately 1/26/2004, 571-272-0902 thereafter.. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

12/12/03

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800 7600